



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,996	02/18/2005	Hiroyuki Asada	05105/HG	3212
1933 7590 10/19/2007 FRISHAUF, HOLTZ, GOODMAN & CHICK, PC 220 Fifth Avenue 16TH Floor NEW YORK, NY 10001-7708			EXAMINER WEBB, WALTER E	
			ART UNIT 4133	PAPER NUMBER
			MAIL DATE 10/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,996	Applicant(s) ASADA ET AL.	
	Examiner Walter E. Webb	Art Unit 4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/27/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-4 are pending and rejected.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1 and 2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Schneider et al. (US 6,011,062).

Applicant argues that because latanoprost is one of 34 prostglandin derivatives of the invention of Schneider, it is not anticipated by the reference. Applicant's arguments are not persuasive. Schneider et al. teach an ophthalmic solution containing the necessary components of Applicant's claims 1 and 2, namely latanoprost at 0.001 (W/V) and a pH between 5.0 and 6.25. (See col. 9, Example 2 (table) and col. 5, line 57.) Applicant cites *In re Rushig*, where the court found hindsight anticipations based on applicant's disclosure, where the prior art lists 130 and 156 variable compounds. However, the list of 34 prostaglandins are more in keeping with the courts opinion in *Petering* (133 USPQ at 280), where the court found that a person of ordinary skill in the art would recognize a specific compound of a list of some 20 compounds in a limited class, where the members of which were very similar in structure and properties. Because Schneider contains a list of compounds (34 in all), of a limited class

Art Unit: 4133

(prostaglandin) where the members are similar in structure and properties, a person of ordinary skill in the art would envisage the specific compound, latanoprost.

Claim Rejections - 35 USC § 103

Claims 1-4 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider et al., (US 6,011,062) in view of Inada et al., (US 5,916,550).

Applicant argues that the Schneider et al., and Inada et al. do not discuss the stability of latanoprost or the advantages of applicant's stabilized ophthalmic solution containing latanoprost. Applicant's arguments are not persuasive, since Schneider lists latanoprost as a type of prostaglandin used to stabilize their ophthalmic solution, and Inada uses ϵ -aminocaproic in its stable ophthalmic composition to aid in maintaining the pH of the solution as well as reducing irritable response in the eye due to prolonged storage (see Inada, col. 1, lines 59-67). The artisan would reasonably expect success in combining the ϵ -aminocaproic of Inada with the ophthalmic solution of Schneider, especially since both references teach ophthalmic solutions, which are both stabilized with the respective components. "[A] person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1390. Further, any adjustment to the concentration of latanoprost or ϵ -aminocaproic is simply routine optimization. It is obvious for one of ordinary skill in the art at the time the invention to adjust ingredients in a composition to optimize the desired results of the composition.

Art Unit: 4133

Applicant points the examiner to Applicant's table 3, but Table 3 does not show unexpected results, since PEG 400 shows 88.8% activity and ϵ -aminocaproic acid shows 93.1% activity. The differences in the percentages are not significant enough to reasonably confer to the artisan that these results are unexpected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 9:00am-5:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

WW



JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER